OFFICE OF SPECIAL MASTERS

April 28, 2003

NANCY GARDNER-COOK,	*	
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	*	No. 99-480V
	*	PUBLISHED
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Petitioner,	*	
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v.	*	
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SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
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	*	
Respondent.	*	
	*	

Daniel H. Shertzer, Sr., Lancaster, PA, for petitioner.
Michael P. Milmoe, Washington, DC, for respondent.

DECISION

MILLMAN, Special Master

Petitioner filed a petition on July 23, 1999 under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10 et seq., alleging that she suffered left-sided numbness after her first hepatitis B vaccination on August 12, 1994, and Guillain-Barre Syndrome (GBS) and/or acute disseminated encephalomyelitis (ADEM) after her second hepatitis B vaccination on September 9, 1994. Pet. at ¶ 2.

Petitioner claims the following sequelae: loss of IQ and of short-term memory, difficulty finding words and reading ordinary text, increase of systemic pain, retrobulbar headaches, spinal pain, autonomic nervous system changes and tachycardia, extreme slowness in the workplace, unusual irritability and clumsiness, hypersomnia with major sleep dysfunction, exhaustion, left-sided numbness and sensation changes, personality changes, distortions of sound, smell, and visual acuity, shortness of breath, gastrointestinal difficulties, flushing, and other symptoms. Pet. at ¶ 3.

With her petition, Ms. Gardner-Cook filed an affidavit stating that her vaccine injury was diagnosed as chronic encephalopathy or encephalomyelopathy which resulted in the sequelae listed in the petition. Affidavit dated July 16, 1999. Respondent denies that hepatitis B vaccine injured petitioner.

On June 19, 2002, the undersigned held a hearing in this case. Testifying for petitioner were Dr. Byron M. Hyde, Nancy Gardner (petitioner), and Robert L. Cook (Ms. Gardner-Cook's husband). Testifying for respondent was Dr. Kottil W. Rammohan.

FACTS

(Because of the highly sensitive nature of the facts contained in Ms. Gardner-Cook's medical records, the undersigned is publishing this opinion without the factual section and is simultaneously issuing an unpublished decision with the factual section.)

TESTIMONY

Dr. Byron M. Hyde testified first for petitioner. He is the principal editor of a test on chronic fatigue and myalgic encephalopmyelitis. Tr. at 5. He is not board-certified in anything and does not earn a living practicing medicine, having an independent source of income (his wife is Secretary of State of Canada). Tr. at 37. He worked in the past as a family practitioner in Canada. Tr. at 8. He

started his adult working life as a geophysicist and went to mine school. Tr. at 9. However, he injured his back in the Arctic and went back to university. Id. He did a two-year internship in neurosurgery and immunology, but not in family medicine. Tr. at 11. He was family doctor for 17 years until 1984. Id. Only since 1984 has he been studying poorly-defined diseases such as chronic fatigue syndrome (CFS) and fibromyalgia. Id.

In 1989, there were the first adverse reactions to the plasma-derived hepatitis B vaccine. Tr. at 12. Ten nurses became ill with something like CFS after receiving hepatitis B vaccine. Id. One had myasthenia gravis. Id. In Quebec, from 1987-90, 65 mostly health care workers had significant untoward reactions to hepatitis B vaccine. Id.

He decided he was not scientifically equipped to understand what was going on with these people. Tr. at 13. He went to the Canadian government office of untoward vaccine reactions and gave them the patients' names and addresses in 1989 or 1990, but the office rejected them. Id. He held a meeting with Merck, but did not give them the 65 cases, although a nurse did. Tr. at 15. Dr. Hyde stated he has seen 200 patients with adverse reactions over the years. Tr. at 17.

Dr. Hyde is not a treating physician but regards himself as an investigative physician. Tr. at 18. He stated that post-recombinant hepatitis B reactions fall into several groups. Id. First it is an exceedingly safe vaccine. Id. Vaccinees with abnormalities differentiate them from others. Tr. at 25. He sees six areas of reaction: (1) type 1 hypersensitivity which can manifest as asthma or eczema (the atopic patient); (2) a preexisting infection, either viral or bacterial; (3) after a prior vaccination with a reaction that a doctor ignored, the patient has a significant untoward reaction to a subsequent vaccination and has chronic disability; (4) a preexisting long-type of hepatitis B leading

to significant reaction due to reactivating the antibody-antigen complex; (5) revaccination leading to untoward reactions; and (6) preexisting or ongoing autoimmune disease. Tr. at 26-34.

Dr. Hyde stated that he does not have the academic and intellectual abilities to understand what he sees among the 200 cases of adverse reactions he has seen. Tr. at 25. Almost all the cases in which Dr. Hyde becomes involved settle. Tr. at 39. If a relative in his family had a neurological disease, he would refer that person to a neurologist. Tr. at 40-1.

Dr. Hyde testified that he did not see that Ms. Gardner-Cook had GBS and ADEM, but her illness resembled them, but also resembled vaccinial encephalomyelitis. Tr. at 35. She is an atopic person with a significant untoward reaction to her first hepatitis B vaccination. Tr. at 42. She should not have been revaccinated since she had a preexisting autoimmune disease. Id. We will never know exactly what happened to her. Id. Corticosteroid removed any ongoing ADEM sequelae from Ms. Gardner-Cook. Tr. at 42-3.

One would need spinal and serum immunoglobulins to diagnose ADEM. Tr. at 43. We do not know if Ms. Gardner-Cook had postvaccinal encephalomyelitis, but she has something that resembles it. Id. She has significant abnormalities and her SPECT scans are still abnormal. Tr. at 44. Hepatitis B caused a hypersensitivity type 3 illness (like rheumatoid arthritis, lupus or polymyositis). Id. Inflammatory reactions to the disease hepatitis B (not the vaccine) cause a vasculitis, which punches holes in the basement membrane. Tr. at 45. When it meets myelin, it increases ANA (Ms. Gardner-Cook's ANA levels are up and down all the time). Id. She has not developed rheumatoid arthritis or lupus. Id. Her IQ went from 120 to 101. Tr. at 46.

Dr. Hyde has sent Sheila Bastien 12 to 14 hepatitis B patients. Id. Ms. Gardner-Cook is one of the two worst patients. Id. Prior to the hepatitis B vaccinations, she had hypothyroidism, an

autoimmune diseases and no period for two years. Tr. at 47. Her resting blood sugar was exceedingly elevated even though she had not eaten for 12 hours. Id. He does not know her actual metabolic state. Id.

Ms. Gardner-Cook's second hepatitis B vaccination caused significant respiratory distress syndrome. Tr. at 49. The lungs are the most vascular organ in the body and a vasculitis reaction would occur in the lungs. Id. This is the classical type 3 hypersensitivity reaction. Tr. at 50. Dr. Hyde opined that Ms. Gardner-Cook had a neuropathy, and that her SPECT and PET scans showed a major CNS disease. Id. She had a positive Romberg's, implicating the posterior tracts of the spinal cord. Tr. at 50-1. Ten days after she received Corticosteroid treatment, the Romberg sign disappeared. Tr. at 51.

She had an ADEM-type illness. Id. Her pre-vaccination history shows a long history of atopic illness (depression). Tr. at 56. Despite all these problems, she always managed to work. Id. Her second reaction to hepatitis B vaccine was worse than her first. Tr. at 57. The PET and SPECT scans look at her level of microvascularization. Tr. at 59. They can tell if there is brain cell function, but cannot tell if this is due to vasculitis or cell defect. Id. The PET is more specific than the SPECT. Petitioner's brain shows holes, i.e., physiological areas with no activity. Tr. at 68. Thus, the left temporal area has a "hole" just like a temporal lobe seizure (it is non-functional). Id. Ms. Gardner-Cook has a large number of substantially non-functional areas of her brain. Id. To Dr. Hyde, vasculitis and neuropathy are the same thing (a type 3 reaction). Tr. at 70.

Ms. Gardner-Cook's brain looks as if it were shot with a shot gun. Tr. at 67. This is not normally found in CFS patients, but is found in post-hepatitis B patients with reactions. Tr. at 70.

Dr. Hyde chairs a foundation to study CFS and myalgic encephalomyelitis, but the foundation is dying. Tr. at 84.

After her first hepatitis B vaccination on Friday, August 12, 1994, Ms. Gardner-Cook's vaccine site became numb and irritated. Tr. at 96. She had numbness in her head and face. Id. The left side of her body, neck, and shoulder felt strange. Id. She was short of breath and had difficulty speaking and focusing her left eye. Id. Her words were slurred. Id. On Monday, she was unsteady. Id. She went to a doctor to rule out multiple sclerosis. Tr. at 97. She had an MRI, which was normal, and she rapidly improved. Id. She was discharged 6 days afterwards. Id. On physical examination, she was noted to have hypothyroidism, mitral valve prolapse, a history of anxiety and depression, a positive Romberg (which is nonspecific–it deals with a sensory area of the spinal cord). Id. She had a sensory defect. Tr. at 98. The impression was a new onset of neurologic symptoms. Tr. at 97. But she did not have a "real" neurological examination. Tr. at 98. Dr. Maxine Montgomery, a neurologist, examined her, but Dr. Hyde testified that this was not a complete neurological examination. Tr. at 99. She should have done a fundoscopic examination and checked for ankle reflexes. Tr. at 99-100.

On September 9, 1994, Ms. Gardner-Cook received her second hepatitis B vaccination. Tr. at 100. She had pain, more down the back, and numbness in her left arm and leg. Id. She had a localized minor reaction of redness, and a temperature of 102 to 103°. Id. She had generalized itching and a hive-like reaction on her face. Id. She had nasal congestion. Tr. at 101. Dr. Martin diagnosed a Marcus Gunn pupil (indicative of a local optic nerve phenomenon), which is a neurological sign. Id. Her ANA had a substantial titer of 1:640. Id. She was short of breath. Id.

The doctor put her on Prednisone for a month. Tr. at 102. Her ANA declined to 1:320 and then to 1:80. Tr. at 104.

Ms. Gardner-Cook does not have rheumatoid arthritis. Tr. at 105-6. She has a history of asthma and eczema, which are IgE-mediated, and fall into type 1 hypersensitivity. Tr. at 106. She also has type 3 hypersensitivity in which the antibody combines with the antigen in the hepatitis B capsule to form an immune complex that can be deposited in the terminal capillaries which are very small. Id. Dr. Hyde she has a brain and probably spinal cord (CNS) injury. Tr. at 107. Ms. Gardner-Cook is chemically hypersensitive and worked with a lot of solvents. Tr. at 112. She quite possibly has lung disease associated with that. Id.

Sheila Bastien did not find that depression was a major factor in Ms. Gardner-Cook's case. Tr. at 113. Ms. Gardner-Cook has significant and relatively severe injury to her cortical (affecting memory and decision-making) and subcortical (affecting coordination) areas. Tr. at 115. She also has a limbic system anomaly as depicted on her PET scan, which ties together the cortical and subcortical areas. Tr. at 116. As for the assertion that depression caused her abnormal SPECT and PET scans, Dr. Hyde said Ms. Gardner-Cook had an area in her left frontal lobe which was inconsistent with depression, but was consistent with emotional volatility, which is seen frequently with ADEM. Tr. at 118-19.

Dr. Hyde said that the cortical, left lower frontal lobe controls some of the immune system and has nothing to do with depression. Tr. at 120. The left posterior parietal is also affected, dealing with visual and auditory functions. Id. Depression shows up in the frontal lobes, but Ms. Gardner-Cook's frontal lobes were not affected. Id. Dr. Hyde concluded that her symptoms are not related to hysteria or depression. Tr. at 124.

Dr. Hyde called himself a "technologist." Tr. at 130. He testified before a workmen's compensation board for petitioner. Tr. at 131. Ms. Gardner-Cook does not have CFS, but she does have a CNS injury. Tr. at 134. He refers a lot of people to Sheila Bastien. Tr. at 136. In Dr. Hyde's opinion, GBS involves the spinal cord which is part of the CNS. Tr. at 137. ADEM is systemic and a CNS injury. Id. Dr. Hyde would have liked if cerebral spinal fluid (CSF) tests and serial MRIs had been done on Ms. Gardner-Cook. Id. He believes that Ms. Gardner-Cook's condition is "GBS-like" and "ADEM-like." Tr. at 138. She has a lot of factors of ADEM, but improved with her treatment course. Id. Not enough was done to diagnose ADEM or GBS in Ms. Gardner-Cook's case. Tr. at 168. He thinks Ms. Gardner-Cook should have been referred to a neuroimmunologist, who would have tested the blood flow to the fine vasculature of her brain and CNS. Id.

Dr. Hyde said he cannot assume that Ms. Gardner-Cook's pre-vaccination symptoms were significant. Tr. at 175. She has a history of left shoulder numbness. Id. After vaccination, she had really abnormal changes in her brain. Tr. at 185-6. After the first vaccination, her symptoms were transient. Tr. at 191. After the second vaccination, her symptoms remained, improving after corticosteroid (pain, pulmonary symptoms, ataxia). Tr at 193. But she still has neuropsychiatric and perceptual problems. Id. The ANA titer can be elevated by hepatitis B virus, rheumatoid arthritis, systemic lupus erythematosis, and polymyalgia. Tr. at 199. It is highly unlikely for someone to be normal and have a persistently elevated ANA titer. Tr. at 198. It means an ongoing antibody reaction against the nucleus of every cell. Tr. at 199. Dr. Hyde is surprised that Ms. Gardner-Cook does not have rheumatoid arthritis or lupus. Tr. at 201. He has too many patients like her not to conclude that she has a hepatitis B injury. Tr. at 202. She may have a pancreatic problem as well as a thyroid problem. Tr. at 205. She weighed 322 pounds. Tr. at 207.

Ms. Nancy Gardner-Cook testified next. Her family has a history of anxiety and panic disorder. Tr. at 208. In 1989, after the birth of her daughter Sarah, she was prescribed Xanax for postpartum depression. Id. Otherwise, Ms. Gardner-Cook denies depression. Tr. at 209. She was agitated and not relaxed when Sarah was born. Id. Ms. Gardner-Cook testified that she has never considered herself depressed. Id.

She received both hepatitis B vaccinations on Friday mornings before work. Tr. at 210. After the first hepatitis B vaccination, her left side was numb. Tr. at 210. The numbness spread. Id. After the second hepatitis B vaccination, her arm hurt right after. Tr. at 211. She became hot, tired, achy, and nauseated, as if she had caught the flu. Id. The next morning, her whole left side was numb. Tr. at 212. She had pain in her lower spine which ascended. Id.

Now, she is tired and cannot complete a task. Tr. at 213. She is on prednisone and contracted diabetes. Id. She gets cramps. Tr. at 215. She currently takes Levoxyl for her thyroid, Allegra, asthma drugs, Prevacid for indigestion, generic Xanax and Paxil for her anxiety disorder. Id. She has adrenal insufficiency. Tr. at 217. After the second hepatitis B vaccination, she had headaches for one week, and then they went away, returning again for one week. Tr. at 225. She gets sinus headaches and light bothers her. Tr. at 225-6. Before the vaccinations, she had tension headaches in the back of her head. Tr. at 226.

Robert L. Cook, Ms. Gardner-Cook's husband, testified next. Tr. at 228. Before she received hepatitis B vaccine, Ms. Gardner-Cook cleaned the house and occasionally cooked. Id. She could multitask. Id. Now she cannot organize. Id. She lacks stamina and is unpredictable. Tr. at 230. She sees, smells, or hears things that are not there. Tr. at 231. She has anxiety disorder. Id. Before the vaccinations, she was gregarious, but not afterwards. Tr. at 232.

Dr. Kottil W. Rammohan, a neuroimmunologist, testified for respondent. Tr. at 233. He is board-certified in neurology, internal medicine, and rehabilitation. Tr. at 235. He is the director of neuroimmunology in his laboratory and specializes in infections and immune disorders of the nervous system, particularly slow viruses in the nervous system. Tr. at 234-5. He was the first fellow at the National Institutes of Health in neuroimmunology and was there for six years. Tr. at 236. Besides his clinical practice, Dr. Rammohan does clinical research involving drug trials and disease mechanisms, and has an autoimmune study of multiple sclerosis (MS) involving voltage dated sodium challenge. Tr. at 237-8. Ninety percent of Dr. Rammohan's patients have MS, suspected MS, or suspected ADEM, lupus, or chronic infections of the brain. Tr. at 234-5.

Dr. Rammohan's opinion in this case is that Ms. Gardner-Cook did not have either ADEM or GBS. Tr. at 239. In fact, she has never had any form of a demyelinating disorder. Id. Moreover, she did not present with CNS vasculitis of the brain. Tr. at 240. If she had had this condition, she would have had increased intracranial pressure. Tr. at 240-1. In order to diagnose ADEM, three criteria must be fulfilled: (1) a clinical examination; (2) a cranial MRI; and (3) a lumbar puncture. Tr. at 241. On pathology, ADEM has marked areas of demyelination and hemorrhage in the brain. Tr. at 242. In the old rabies vaccine (made from rabbits' spinal cord), a number of patients got ADEM (the animal model of which is EAE). Tr. at 242.

GBS is not a disorder of the spinal cord, contrary to Dr. Hyde's testimony. Tr. at 243. It is a peripheral nervous system disorder, sparing the brain and spinal cord. Id. Its animal analogue is EAN. Id. It is characterized by fulminant demyelination. Tr. at 243-4.

The reason that Ms. Gardner-Cook did not receive a spinal tap was that her MRI was normal. Tr. at 244. She did not have fulminant demyelinating disorder of the brain. Tr. at 245. SPECT and

PET are not the standard of care in a clinical practice to diagnose these diseases. Tr. at 247. An abnormal SPECT can be related to drugs such as Xanax and to depression. Id. They modify glucose uptake, which is what SPECT measures. Id. If a patient were to stop taking Xanax, she could go into acute withdrawal and her blood pressure would rise through the roof. Id. Both Xanax and migraines affect SPECT and PET scan results. Tr. at 248.

Ms. Gardner-Cook had immediate reactions to hepatitis B vaccine, but no brain abnormality. Tr. at 250. Her symptoms ended within 48 to 72 hours after vaccination. Tr. at 252. She may have small emboli from mitral valve prolapse which explains her symptoms. Tr. at 251. Dr. Rammohan concurs with Dr. Snyder's opinion in the case which attributes Ms. Garner-Cook's symptoms to depression. Id.

Dr. Rammohan sees 10 ADEM patients a year. Tr. at 251. GBS is rarer and he sees 2 patients a year with it. Tr. at 251-2. Ms. Gardner-Cook does not have any symptoms that satisfy the criteria for GBS. Tr. at 255. She had a reactivation of bronchospasm after the vaccination, but not type 3 hypersensitivity. Tr. at 258. For type 3 hypersensitivity, one needs to show antibody-antigen complex in the organ with or without complement. Tr. at 257. Ms. Gardner-Cook is not allergic to yeast (the RAST test). Tr. at 266. Hepatitis B vaccine is made with yeast. Id. We all have autoantibodies. Id. Ms. Gardner-Cook's ANA would have been positive before she received hepatitis B vaccine. Tr. at 268. It is unrelated to her symptoms. Id.

A Marcus Gunn pupil is an abnormal second optic nerve. Tr. at 269-70. Ms. Gardner-Cook was not blind in the eye and did not have a unilateral optic nerve problem. Tr. at 271. She could see. Id. She did not have optic neuritis. Id. She did not have neurological difficulties. Tr. at 276. Dr.

Hyde's opinion is not mainstream medical thinking. Tr. at 286. One cannot have a neurological disease without a diagnosis. Tr. at 289. GBS does not have a pattern in the brain. Id.

PET scans do not define the function of the brain and are not used for diagnosis. Tr. at 292. SPECT scans are useful for showing blood flow problems, but they are not done in ADEM patients. Tr. at 292-3. They are done in cases of Alzheimer's, language disorders, and persistent and severe loss of function to help diagnoses. Tr. at 293. Because PET and SPECT scans have great variability, one needs serial scan to see a sequential basis or pattern. Tr. at 298-9. The results can change with exercise and the use of agents that depress function in the brain. Tr. at 301.

Dr. Rammohan testified that depression can cause cognitive decline. Tr. at 303. Ms. Gardner-Cook had preexisting depression. Id. If she had fever three days after her vaccination, it is not vaccine-related. Tr. at 314-5. She did not have encephalomyelitis. Tr. at 315. She may have had migraine because of photophobia and seeing things further away than they were. Tr. at 316. Brachial neuritis has a different picture and usually does not affect the whole arm. Tr. at 317. Her breathing problems had nothing to do with GBS. Tr. at 318. Her neurological examination was not significantly abnormal. Tr. at 325. Her clinical course was mild. Tr. at 327.

With ADEM, patients become paralyzed and sometimes end up on a ventilator. Id. Some die. Id. Ms. Gardner-Cook did not have a mild form of ADEM or GBS. Tr. at 330. Her symptoms were subjective. Id. It is conjecture that she had such small lesions, they did not show up on MRI. Tr. at 340-1. She did not have anaphylaxis because three days elapsed. Tr. at 341. Dr. Rammohan cannot conceive of a neurologic injury without objective signs. Tr. at 344. One uses the word "neuropathy" on for peripheral nervous system disease, not CNS disease. Tr. at 348. A PET scan

can show abnormalities in encephalopathy. Tr. at 350. Loss of myelin does not equal loss of function. Tr. at 352.

DISCUSSION

Petitioner is proceeding on a theory of causation in fact. To satisfy her burden of proving causation in fact, petitioner must offer "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect." Grant v. Secretary, HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Agarwsal v. Secretary, HHS, 33 Fed. Cl. 482, 487 (1995); see also Knudsen v. Secretary, HHS, 35 F.3d 543, 548 (Fed. Cir. 1994); Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993).

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, supra, 956 F.2d at 1149.

Petitioner must not only show that but for the vaccine she would not have had the injury, but also that the vaccine was a substantial factor in bringing about her injury. Shyface v. Secretary, HHS, 165 F.3d 1344 (Fed. Cir. 1999).

In essence, the special master is looking for a reputable medical explanation of a logical sequence of cause and effect (Grant, supra, 956 F.2d at 1148), and medical probability rather than certainty (Knudsen, supra, 35 F.3d at 548-49).

As the Federal Circuit stated in Knudsen, supra, 35 F.3d at 548, “Causation in fact under the Vaccine Act is thus based on the circumstances of the particular case, having no hard and fast *per se* scientific or medical rules.”

Essential to petitioner's satisfying her burden of proof that hepatitis B caused her injury is the opinion of a valid medical expert. Thus, the opinion of Sheila Bastien, a Ph.D., that Ms. Gardner-Cook suffered neurologic injury is not admissible because she is not a medical doctor. See Domeny v. Secretary, HHS, No. 94-1086V, 1999 WL 199059 (Fed. Cl. Spec. Mstr. March 15, 1999), aff'd, (Fed. Cl. May 25, 1999) (unpublished), aff'd, No. 99-5130 (Fed. Cir. April 10, 2000) (per curiam) (unpublished) (proffer of dentist's testimony for diagnosis of a neuropathy rejected).

Ms. Gardner-Cook's expert witness is Dr. Byron M. Hyde who terms himself a "technologist" or an "investigative physician." He has not practiced medicine since 1984, and when he did practice medicine, it was in family practice, not in neurology or neuroimmunology. Dr. Hyde has never been board-certified in any specialty. He is in the fortunate position of not having to earn a living, and so devotes his time to litigation and helping people who assert that hepatitis B vaccine has injured them. Dr. Hyde's testimony strongly suggests that he is alone against the mainstream of the medical establishment, a status he regards as a mark of honor. He has associated himself with some like-minded people, including Sheila Bastien, and by a process of misdiagnosis and misinterpretation, has cast aspersions on hepatitis B vaccine in the legal arena. It may well be that hepatitis B vaccine causes adverse reactions, but Dr. Hyde's opinion in this case is highly suspect and not credible.

Dr. Hyde opined that Ms. Gardner-Cook had GBS and/or ADEM. When challenged with the total lack of clinical symptoms and signs that would support such diagnoses, he retreated and said it did not really matter whether she had GBS and/or ADEM, and then concluded that, in any event, she did have one or the other. He also opined that large-scale demyelination can occur that present technology cannot demonstrate, a statement that seems contrary to accepted medical knowledge.

In Dr. Hyde's mind, vasculitis and neuropathy are the same thing. He thinks that Ms. Gardner-Cook has holes in her brain as detected by her SPECT and PET scans. He ignores her prevaccination history of anxiety, depression, numbness, fatigue, obesity, hypothyroidism, mitral valve prolapse, aches, light-headedness, dizziness, difficulty sleeping, exhaustion, failure to concentrate, headaches, feeling wiped out, photophobia, and chest pains. To him, all that is important is that Ms. Gardner-Cook worked before receiving hepatitis B vaccine and now she does not work. He thinks she should have been sent to a neuroimmunologist.

Dr. Kottil W. Rammohan, respondent's expert, is a neuroimmunologist. He is board-certified in neurology, internal medicine, and rehabilitation. He is the director of neuroimmunology in his laboratory and specializes in infections and immune disorders of the nervous system. He was the first fellow at the National Institutes of Health in neuroimmunology where he stayed for six years. He has a clinical practice and does research. His C.V. is filled with professional medical articles published in peer-reviewed journals, rather than the cases in which he has testified.

Dr. Rammohan is the very specialist that Dr. Hyde testified Ms. Gardner-Cook should have seen. Dr. Rammohan testified that Ms. Gardner-Cook did not have either GBS or ADEM. She never had any type of demyelinating disorder. She also did not have vasculitis in her brain. Although Dr. Hyde does not seem to realize that GBS, being a peripheral nervous system disease, does not affect the brain, Dr. Rammohan testified that GBS spares the brain and spinal cord. Ms. Gardner-Cook had a normal MRI. She did not have a fulminant demyelinating disorder of her brain. The SPECT and PET scans are not used to diagnose demyelinating diseases but to detect glucose uptake and blood flow. Drugs can affect the results of these scans, and Ms. Gardner-Cook takes the

type of drugs which can affect these results. Moreover, she has a long history of depression which can also affect the results of these scans.

Dr. Rammohan's impression of Ms. Gardner-Cook's medical condition and interpretation of her tests is supported in the record by the opinions of Dr. Jack W. Snyder, a toxicologist and Associate Professot of Emergency Medicine, and Dr. Mark Kritchevsky, a Professor of Neurosciences. Dr. Snyder opined that Ms. Gardner-Cook's condition is due to her prevaccination problems and the treatments (i.e., steroids) she has received for them. He noted that on physical examination, she was normal. Her hypertension, sinusitis, colitis, mitral valve prolapse, depression, obesity, and bronchitis predated hepatitis B vaccine.

After he read the interpretations of the SPECT and PET scans, Dr. Snyder opined that Dr. Hyde and the radiologists had misinterpreted her condition. These scans assess variations in blood flow to the brain. One cannot use them to conclude that a brain has been damaged or injured because blood flow variations occur each moment in everyone's brain. Dr. Snyder said there is no objective evidence of injury to Ms. Gardner-Cook's brain. He stated that her PET and SPECT scans are consistent with those of depressed people.

No aspect of Ms. Gardner-Cook's neurological examination supports a diagnosis of either demyelination or vasculitis. Dr. Snyder's examination of Ms. Gardner-Cook confirmed she has depression. There is no objective evidence that she has encephalopathy.

Dr. Kritchevsky stated that, on mental status examination, Ms. Gardner-Cook was alert with normal attention and in good spirits. He tested her memory in a number of ways and she performed quickly, confidently, and correctly. Her muscle tone, reflexes, balance, posture, gait, and strength were normal. Dr. Kritchevsky noted that the information form that Dr. Hyde had Ms. Gardner-Cook

fill out was highly biased and more suitable for collecting information for a plaintiff's attorney than for obtaining any sort of research data.

Dr. Kritchevsky's opinion of Ms. Gardner-Cook's abilities matches the impression the undersigned had on seeing and hearing Ms. Gardner-Cook testify. She was an excellent witness, poised, intelligent, without hesitation or inability to remember. However, she denied she had a prevaccination history of depression. Considering that her medical records show six instances from 1989 through 1993 of Ms. Gardner-Cook's having depression, her testimony is not credible.

Well-established case law holds that information in contemporary medical records is more believable than that produced years later at trial. United States v. United States Gypsum Co., 333 U.S. 364, 396 (1948); Burns v. Secretary, HHS, 3 F.3d 415 (Fed. Cir. 1993); Ware v. Secretary, HHS, 28 Fed. Cl. 716, 719 (1993); Estate of Arrowood v. Secretary, HHS, 28 Fed. Cl. 453 (1993); Murphy v. Secretary, HHS, 23 Cl. Ct. 726, 733 (1991), aff'd, 968 F.2d 1226 (Fed. Cir.), cert. denied sub nom. Murphy v. Sullivan, 113 S. Ct. 263 (1992); Montgomery Coca-Cola Bottling Co. v. United States, 615 F.2d 1318, 1328 (1980). Contemporaneous medical records are considered trustworthy because they contain information necessary to make diagnoses and determine appropriate treatment:

> Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.

Cucuras v. Secretary, HHS, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Dr. Rammohan testified that Ms. Gardner-Cook had immediate reactions to hepatitis B vaccine,[1] but no brain abnormality. He stated that her symptoms ended within 48 to 72 hours after vaccination. He agrees with Dr. Snyder in attributing most of her symptoms to depression although her mitral valve prolapse may be causing small emboli to form. Depression can cause cognitive decline.

Dr. Rammohan stated that Ms. Gardner-Cook's elevated ANA would have been positive before she received hepatitis B vaccine and was unrelated to her symptoms. She did not have optic neuritis or any neurological difficulties. GBS is a peripheral nervous system disease with bilateral paralysis. ADEM is a central nervous system disease with multiple lesions in the brain and spine, causing paralysis. Dr. Rammohan cannot conceive of a neurologic injury without objective signs, and Ms. Gardner-Cook did not have any.

Dr. Hyde was asked at the hearing what he would do if someone in his family had a neurologic injury. He responded that he would refer that person to a neurologist. Dr. Hyde also stated that he did not initially see himself as having the academic and intellectual abilities to understand the people who came to him claiming an adverse vaccine reaction.

Dr. Hyde is a charming and urbane person, but his medical skills are limited, his opinion is outside contemporary medical opinion (and family practitioners should not offer expert opinions about demyelinating diseases), and he is tainted by a bias toward finding a causative nexus regardless of the facts of the individual case. He is unqualified to give an opinion here.

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[1] Of note is Ms. Gardner-Cook's initial complaint to a nurse on the Friday she received her first hepatitis B vaccination that her arm and shoulder numbness began over the weekend, which raises the possibility of onset prior to vaccination. In any event, Ms. Gardner-Cook complained about her arms and legs being numb in a letter Dr. Stephen Diamonti received from her during a visit for depression and anxiety on May 4, 1989, five years before vaccination.

Dr. Rammohan, as well as Dr. Snyder and Dr. Kritchevsky, are professionals capable of proffering appropriate opinions. Dr. Rammohan specializes in demyelinating diseases. He has a clinical practice and does research. He is board-certified, productive, and accomplished. He is knowledgeable about neuroimmunology and totally credible. Dr. Snyder's and Dr. Kritchevsky's opinions support Dr. Rammohan's testimony that Ms. Gardner-Cook does not have a brain injury or any neurological disease. Comparing Dr. Hyde to respondent's experts leads to the inescapable conclusion that petitioner has not put on a credible case of vaccine injury.

The undersigned holds that petitioner has failed to prove a prima facie case that hepatitis B vaccine injured her neurologically or caused any illness whose sequelae lasted more than six months (as the statute requires: 42 U.S.C. § 300aa-11(c)(1)(D)). Ms. Gardner-Cook has had a hard life, filled with medical conditions (such as depression and obesity) which have led to many of her current problems. But she is not physically injured from the hepatitis B vaccination and, if as Dr. Rammohan testified, she had any injury at all, it did not last more than six months.

CONCLUSION

This case is dismissed with prejudice. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment in accordance herewith.

IT IS SO ORDERED.

_____ _____

DATE Laura D. Millman
Special Master